Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Budesonide

December 2025

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Active Ingredient: Budesonide

Dosage Form: Suspension

Route: Inhalation

Strengths: 0.25 mg/2 mL; 0.5 mg/2 mL; 1 mg/2 mL

Recommended Studies: Three in vitro bioequivalence studies

FDA recommends that prospective applicants conduct the following in vitro bioequivalence studies for all strengths of the test product and reference standard (RS) using a standard jet nebulizer with a mouthpiece connected to an air compressor.[1] For each strength, use at least three batches each of the test product and RS, with no fewer than 10 units from each batch. FDA recommends that three primary stability batches be also used to demonstrate in vitro bioequivalence. The three batches of test product should be manufactured from, at a minimum, three different batches of drug substance(s) and excipient(s).

1. Type of study: Delivered dose (DD)
   Design: The DD study should be performed as per Drug Substance Delivery Rate and Total Drug Substance Delivered test described in the United States Pharmacopeia General Chapter <1601> Products for Nebulization—Characterization Tests (USP <1601>) using a suitably validated low-resistance filter and breathing simulator that is able to generate the child breathing profile specifications as per USP <1601> Table 1. DD is defined dose emitted from the mouthpiece and collected on the filter and filter

[1] The same standard jet nebulizer with a mouthpiece and air compressor should be used when testing the test product and RS and be the same across the in vitro bioequivalence studies.

holders, as applicable. The number of ampules per determination should be one. DD measurements should be reported as mass units and as percent nominal dose.

Bioequivalence based on: Population bioequivalence (PBE) analysis of DD. Refer to the appendix for additional information regarding PBE analysis procedures.

2. Type of study: Nebulization time (NT)
Design: The NT study should be performed as per Drug Substance Delivery Rate and Total Drug Substance Delivered described in USP <1601> using a suitably validated low-resistance filter and breathing simulator that is able to generate the child breathing profile specifications as per USP <1601> Table 1. NT is defined as the time interval used for total drug substance collection per unit, e.g., from the start of nebulization until the mist is no longer coming out of the mouthpiece. The number of ampules per determination should be one.

Bioequivalence based on: PBE analysis of NT.

3. Type of study: Aerodynamic particle size distribution (APSD)
Design: The APSD study should be performed using a flow rate of 15 L/min using the Next Generation Impactor (NGI) without pre-separator as described in USP <601> following the method described for Aerodynamic Assessment of Nebulized Aerosols described in USP <1601>, or another appropriate method, to determine APSD using a validated assay. Water evaporation should be minimized by performing the APSD study under high humidity conditions (as close as possible to 100% relative humidity), by cooling the cascade impactor to low temperatures (e.g., 5°C), or by any other suitable method.

Additional comments: Drug deposition on individual sites, including the mouthpiece adapter, the induction port, each stage of the cascade impactor and the filter, is requested. Mass balance accountability should be reported based on the sum of all deposition sites. For electronic submission of the individual cascade impactor data for the test product and RS, please provide a table using the format in the appendix and send them as part of the abbreviated new drug application (ANDA) submission.

Bioequivalence based on: PBE analysis of impactor-sized mass (ISM).[2] The cascade impactor profiles representing drug deposition on the individual stages of the cascade impactor along with the mass median aerodynamic diameter (MMAD), geometric standard deviation (GSD), and fine particle mass (FPM) should be submitted as supportive evidence for equivalent APSD.

[2] ISM is defined as a sum of the drug mass on all stages of the cascade impactor plus the terminal filter but excluding the top cascade impactor stage because of its lack of a specified upper cutoff size limit.

Additional information:

Formulation:
To demonstrate bioequivalence, the test product should contain no difference in inactive ingredients or in other aspects of the formulation relative to the RS that may significantly affect the local or systemic availability of the active ingredient. For example, the test product can be qualitatively (Q1)[3] and quantitatively (Q2)[4] the same as the RS to satisfy no difference in inactive ingredients.

Document History: Recommended September 2012; Revised December 2025

Unique Agency Identifier: PSG_020929

[3] Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the RS.
[4] Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ± 5% of those used in the RS.

APPENDIX

Recommendation Related to the Population Bioequivalence (PBE) Statistical Analysis Procedure Used in Bioequivalence Determination of Budesonide Suspension Inhalation Product:

A. Step-wise Procedure of the PBE Computation:

Step 1. Establish population BE criterion:

Population BE criterion:

$$\frac{(\mu_T-\mu_R)^2+({\sigma_T}^2-\sigma_R^2)}{{\sigma_R}^2}\le\theta \quad \textbf{or} \quad \frac{(\mu_T-\mu_R)^2+({\sigma_T}^2-\sigma_R^2)}{{\sigma_{T0}}^2}\le\theta$$

Linearized Criteria**:**

$$\eta_1=(\mu_T-\mu_R)^2+({\sigma_T}^2-\sigma_R^2)-\theta_p\cdot\sigma_R^2<0 \qquad \textbf{for } \sigma_R>\sigma_{T0}$$

$$\eta_2=(\mu_T-\mu_R)^2+({\sigma_T}^2-\sigma_R^2)-\theta_p\cdot{\sigma_{T0}}^2<0 \qquad \textbf{for } \sigma_R\le\sigma_{T0}$$

Where,

$\mu_T-\mu_R$: Mean difference of T (log scale) and R (log scale) products

${\sigma_T}^2, {\sigma_R}^2$: Total variance of T and R products

σ_{TO}: Regulatory constant ($\sigma_{TO}=0.1$)

θ_{p}: Regulatory constant ($\theta_{\mathrm{p}}=2.0891$) calculated as following:

$$\frac{[\ln(1.11)]^2+0.01}{0.1^2}=2.089$$

Estimating the Linearized Criteria:

$$\hat{\eta}_1=\hat{\Delta}^2+\frac{MSB_T}{m}+\frac{(m-1)MSW_T}{m}-\left(1+\theta_p\right)\frac{MSB_R}{m}-\left(1+\theta_p\right)\frac{(m-1)MSW_R}{m} \quad \textbf{for } \sigma_R>\sigma_{T0}$$

$$\hat{\eta}_2=\hat{\Delta}^2+\frac{MSB_T}{m}+\frac{(m-1)MSW_T}{m}-\frac{MSB_R}{m}-\frac{(m-1)MSW_R}{m}-\theta_p{\sigma_{T0}}^2 \quad \textbf{for } \sigma_R\le\sigma_{T0}$$

Where,

$\widehat{\Delta}=\bar{X}_{..T.}-\bar{X}_{..R}$.

m: number of life stages

$\mathrm{MSW_T}$: within-bottle variability for test product

$\mathrm{MSW_R}$: within-bottle variability for reference product

$(\mathrm{MSB_T}-\mathrm{MSW_T})/\mathrm{m}$: between-bottle variability for test product

$(\mathrm{MSB_R}-\mathrm{MSW_R})/\mathrm{m}$: between-bottle variability for reference product

Step 2. Calculate MSB and MSW:

Calculation for MSW_T, MSW_R, MSB_T and MSB_R can be conducted as follows.

$$MSB_k = \frac{m \cdot \sum_{j=1}^{\ell_k} \sum_{i=1}^{n_k} \left(\overline{X}_{ijk.} - \overline{X}_{..k.}\right)^2}{n_k \cdot \ell_k - 1}$$ k refers to either test or reference product

$$MSW_k = \frac{\sum_{j=1}^{\ell_k} \sum_{i=1}^{n_k} \sum_{s=1}^{m} \left(X_{ijks} - \bar{X}_{ijk.}\right)^2}{n_k \cdot \ell_k \cdot (m-1)}$$

$$\bar{X}_{ijk.} = \frac{\sum_{s=1}^{m} X_{ijks}}{m};\ \bar{X}_{..k.} = \frac{\sum_{i=1}^{\ell_k} \sum_{j=1}^{n_k} \bar{X}_{ijk.}}{n_k \cdot \ell_k}$$

n_T, n_R: Number of canisters or bottles per batch, for test and reference products
ℓ_T, ℓ_R: Number of batches of test and reference products
X_{ijks} is the i^{th} bottle in batch #j at life stages for test or reference product;
$\bar{X}_{ijk.}$ is the average m life stages for i^{th} bottle in batch #j;
$\bar{X}_{..k.}$ is the population mean for the reference or test products.

Step 3. Calculate σ_R and σ_T

1) σ_R can be conducted as follow:

$$\sigma_R = \sqrt{\frac{MSB_R}{m} + \frac{(m-1)MSW_R}{m}}$$

a. If $\sigma_R > \sigma_{TO}$ (regulatory constant, 0.1), using the reference-scaled procedure to determine BE for the measured parameter(s)
b. If $\sigma_R \leq \sigma_{TO}$ (regulatory constant, 0.1), using the constant-scaled procedure to determine BE for the measured parameter(s)

2) σ_T can be conducted as follow:

$$\sigma_T = \sqrt{\frac{MSB_T}{m} + \frac{(m-1)MSW_T}{m}}$$

Step 4. Calculate linearized point estimate and 95% upper confidence bound:

1) Reference-scaled Criterion ($\hat{\eta}_1$): Use $\alpha = 0.05$ for a 95% upper confidence bound:
Equation for Linearized Point Estimate:
$Eq = E_D + E1 + E2 + E3s + E4s$
95% upper confidence bound ($H\eta_1$) :
$H\eta_1 = (E_D + E1 + E2 + E3s + E4s) + (U_D + U1 + U2 + U3s + U4s)^{½}$

Following are the equations to compute each component:

E_q = Point Estimate	H_q = Confidence Bound	$U_q = (H_q - E_q)^2$
$E_D = \hat{\Delta}^2$	$H_D = \left(\lvert\hat{\Delta}\rvert + t_{1-\alpha, n_T \cdot \ell_T + n_R \cdot \ell_R - 2} \left(\frac{MSB_T}{n_T \cdot \ell_T \cdot m} + \frac{MSB_R}{n_R \cdot \ell_R \cdot m} \right)^{1/2} \right)^2$	U_D
$E1 = \frac{MSB_T}{m}$	$H1 = \frac{(\ell_T \cdot n_T - 1) \cdot E1}{\chi^2_{\ell_T \cdot n_T - 1, \alpha}}$	$U1$
$E2 = \frac{(m-1) \cdot MSW_T}{m}$	$H2 = \frac{\ell_T \cdot n_T \cdot (m-1) \cdot E2}{\chi^2_{\ell_T \cdot n_T \cdot (m-1), \alpha}}$	U2
$E3s = -(1+\theta_p)\frac{MSB_R}{m}$	$H3s = \frac{(\ell_R \cdot n_R - 1) \cdot E3s}{\chi^2_{\ell_R \cdot n_R - 1, 1-\alpha}}$	U3s
$E4s = -(1+\theta_p)\frac{(m-1)MSW_R}{m}$	$H4s = \frac{\ell_R \cdot n_R \cdot (m-1) \cdot E4s}{\chi^2_{\ell_R \cdot n_R \cdot (m-1), 1-\alpha}}$	U4s

Where $\boldsymbol{\chi^2_{\ell_T \cdot n_T - 1, \alpha}}$ is from the cumulative distribution function of the chi-square distribution with $\ell_T \cdot \boldsymbol{n}_T - 1$ degrees of freedom, i.e. $\Pr(\boldsymbol{\chi^2_{\ell_T \cdot n_T - 1}} \leq \boldsymbol{\chi^2_{\ell_T \cdot n_T - 1, \alpha}}) = \boldsymbol{\alpha}$

For data collected on one life stage (m = 1), ignore E2 and E 4s and their corresponding H and U terms in the calculation. For data collected on more than one stage ($m \geq 2$), use the equations listed above.

2) <u>Constant-scaled Criterion ($\hat{\eta}_2$) : Use $\alpha = 0.05$ for a 95% upper confidence bound:</u>

Equation for Linearized Point Estimate:
$E_q = E_D + E1 + E2 + E3c + E4c - \theta_p {\sigma_{T0}}^2$
95% upper confidence bound ($H\eta_2$) :
$H\eta_2 = (E_D + E1 + E2 + E3c + E4c - \theta_p {\sigma_{T0}}^2) + (U_D + U1 + U2 + U3c + U4c)^{1/2}$

Following are the equations to compute each component:

E_q = Point Estimate	H_q = Confidence Bound	$U_q = (H_q - E_q)^2$
$E_D = \hat{\Delta}^2$	$H_D = \left(\lvert\hat{\Delta}\rvert + t_{1-\alpha, n_T \cdot \ell_T + n_R \cdot \ell_R - 2} \left(\frac{MSB_T}{n_T \cdot \ell_T \cdot m} + \frac{MSB_R}{n_R \cdot \ell_R \cdot m} \right)^{1/2} \right)^2$	U_D
$E1 = \frac{MSB_T}{m}$	$H1 = \frac{(\ell_T \cdot n_T - 1) \cdot E1}{\chi^2_{\ell_T \cdot n_T - 1, \alpha}}$	U1
$E2 = \frac{(m-1) \cdot MSW_T}{m}$	$H_2 = \frac{\ell_T \cdot n_T \cdot (m-1) \cdot E2}{\chi^2_{\ell_T \cdot n_T \cdot (m-1), \alpha}}$	U2
$E3c = -\frac{MSB_R}{m}$	$H3c = \frac{(\ell_R \cdot n_R - 1) \cdot E3c}{\chi^2_{\ell_R \cdot n_R - 1, 1-\alpha}}$	U3c
$E4c = -\frac{(m-1)MSW_R}{m}$	$H4c = \frac{\ell_R \cdot n_R \cdot (m-1) \cdot E4rc}{\chi^2_{\ell_R \cdot n_R \cdot (m-1), 1-\alpha}}$	U4c

For data collected on one life stage ($m = 1$), ignore E2 and E4c and their corresponding H and *U* terms in the calculation. For data collected on more than one stage ($m \geq 2$), use the equations listed above.

The method of obtaining the upper confidence bound is based on two FDA guidances: (1) *Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Posted on August 18, 1999*[a], accompanying to the FDA guidance for industry on *Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action*[a]; and (2) the FDA guidance for industry on *Statistical Approaches to Establishing Bioequivalence*[a]. The concept is adapted from the method for the two-sequence, four-period study design using test-distribution.

Step 5. For the test product to be bioequivalent to the reference product, the following condition must be satisfied:

The 95% upper confidence bound for linearized criteria Hη must be ≤ 0.

B. An Example of PBE Computation:

Study Design: The data given in this example are simulated. A parallel design with two products (test or reference) including 3 batches and 10 bottles/containers per batch for each product with three life stages (beginning, middle and end).

Batches	Container	Stage	Product	In vitro measurement
1	31	B	REF	5.957211
1	31	M	REF	5.961802
1	31	E	REF	5.967178
1	32	B	REF	6.010251

1	32	M	REF	6.004711
1	32	E	REF	6.004797
1	33	B	REF	5.884161
1	33	M	REF	5.894085
1	33	E	REF	5.895977
1	34	B	REF	5.624705
1	34	M	REF	5.632991
1	34	E	REF	5.614428
1	35	B	REF	5.957329
1	35	M	REF	5.966059
1	35	E	REF	5.968143
1	36	B	REF	5.074298
1	36	M	REF	5.063063
1	36	E	REF	5.058519
1	37	B	REF	5.418587
1	37	M	REF	5.420591
1	37	E	REF	5.418178
1	38	B	REF	6.325178
1	38	M	REF	6.321954
1	38	E	REF	6.303148
1	39	B	REF	5.656286
1	39	M	REF	5.68025
1	39	E	REF	5.675036
1	40	B	REF	5.792299
1	40	M	REF	5.775161
1	40	E	REF	5.793083
2	41	B	REF	5.601033
2	41	M	REF	5.611223
2	41	E	REF	5.601142
2	42	B	REF	5.61553
2	42	M	REF	5.587412
2	42	E	REF	5.591004
2	43	B	REF	5.682466
2	43	M	REF	5.676472
2	43	E	REF	5.671434
2	44	B	REF	5.844336
2	44	M	REF	5.855172
2	44	E	REF	5.862329
2	45	B	REF	5.898151
2	45	M	REF	5.883657
2	45	E	REF	5.878956
2	46	B	REF	6.100662
2	46	M	REF	6.105463
2	46	E	REF	6.108098
2	47	B	REF	6.294753
2	47	M	REF	6.28534
2	47	E	REF	6.302333
2	48	B	REF	5.638072

2	48	M	REF	5.627372
2	48	E	REF	5.623516
2	49	B	REF	5.113562
2	49	M	REF	5.122454
2	49	E	REF	5.109271
2	50	B	REF	5.932752
2	50	M	REF	5.913438
2	50	E	REF	5.912427
3	51	B	REF	5.961947
3	51	M	REF	5.955332
3	51	E	REF	5.943721
3	52	B	REF	6.2334
3	52	M	REF	6.250689
3	52	E	REF	6.219668
3	53	B	REF	6.041431
3	53	M	REF	6.038234
3	53	E	REF	6.080464
3	54	B	REF	6.049713
3	54	M	REF	6.039759
3	54	E	REF	6.054218
3	55	B	REF	6.834563
3	55	M	REF	6.85264
3	55	E	REF	6.857395
3	56	B	REF	4.864966
3	56	M	REF	4.907521
3	56	E	REF	4.891049
3	57	B	REF	5.895176
3	57	M	REF	5.885851
3	57	E	REF	5.874895
3	58	B	REF	6.45826
3	58	M	REF	6.443113
3	58	E	REF	6.435882
3	59	B	REF	6.090533
3	59	M	REF	6.102835
3	59	E	REF	6.077606
3	60	B	REF	5.886724
3	60	M	REF	5.920949
3	60	E	REF	5.915749
4	1	B	TEST	6.894594
4	1	M	TEST	6.913011
4	1	E	TEST	6.895764
4	2	B	TEST	5.832334
4	2	M	TEST	5.846562
4	2	E	TEST	5.832269
4	3	B	TEST	6.235755
4	3	M	TEST	6.26231
4	3	E	TEST	6.245095
4	4	B	TEST	5.646185

4	4	M	TEST	5.635887
4	4	E	TEST	5.63034
4	5	B	TEST	5.960711
4	5	M	TEST	5.962902
4	5	E	TEST	5.961959
4	6	B	TEST	5.500354
4	6	M	TEST	5.508444
4	6	E	TEST	5.513115
4	7	B	TEST	6.663099
4	7	M	TEST	6.64733
4	7	E	TEST	6.651215
4	8	B	TEST	5.724774
4	8	M	TEST	5.72086
4	8	E	TEST	5.71411
4	9	B	TEST	6.183375
4	9	M	TEST	6.186433
4	9	E	TEST	6.182109
4	10	B	TEST	5.64053
4	10	M	TEST	5.648589
4	10	E	TEST	5.626395
5	11	B	TEST	6.69764
5	11	M	TEST	6.71128
5	11	E	TEST	6.699829
5	12	B	TEST	6.555609
5	12	M	TEST	6.549935
5	12	E	TEST	6.551611
5	13	B	TEST	5.009683
5	13	M	TEST	5.013969
5	13	E	TEST	5.010928
5	14	B	TEST	5.440976
5	14	M	TEST	5.42057
5	14	E	TEST	5.447687
5	15	B	TEST	6.477609
5	15	M	TEST	6.456082
5	15	E	TEST	6.448981
5	16	B	TEST	6.442601
5	16	M	TEST	6.426217
5	16	E	TEST	6.436262
5	17	B	TEST	5.640496
5	17	M	TEST	5.63846
5	17	E	TEST	5.640755
5	18	B	TEST	6.597718
5	18	M	TEST	6.599232
5	18	E	TEST	6.609437
5	19	B	TEST	6.007241
5	19	M	TEST	5.990695
5	19	E	TEST	5.984292
5	20	B	TEST	6.781806

5	20	M	TEST	6.774386
5	20	E	TEST	6.784001
6	21	B	TEST	5.993852
6	21	M	TEST	5.994287
6	21	E	TEST	5.993541
6	22	B	TEST	6.012322
6	22	M	TEST	6.006182
6	22	E	TEST	6.017961
6	23	B	TEST	5.965969
6	23	M	TEST	5.97125
6	23	E	TEST	5.967839
6	24	B	TEST	5.592609
6	24	M	TEST	5.581154
6	24	E	TEST	5.588877
6	25	B	TEST	6.002182
6	25	M	TEST	6.011583
6	25	E	TEST	6.018746
6	26	B	TEST	5.267014
6	26	M	TEST	5.272291
6	26	E	TEST	5.265213
6	27	B	TEST	5.766104
6	27	M	TEST	5.786727
6	27	E	TEST	5.773194
6	28	B	TEST	6.054975
6	28	M	TEST	6.05232
6	28	E	TEST	6.061088
6	29	B	TEST	5.838689
6	29	M	TEST	5.837566
6	29	E	TEST	5.842508
6	30	B	TEST	5.784255
6	30	M	TEST	5.789891
6	30	E	TEST	5.788662

Following the step-wise PBE computation procedure outlined above, the following components can be determined:

Reference-scaled:

Eq related intermediate parameters	**Hq related intermediate parameters**	**$\mathbf{U_q}$ related intermediate parameters**	$\mathbf{H\eta = Eq + (Uq)^{1/2}}$
$E_D = 0.022094106$	$H_D = 0.113976896$	$U_D = 0.008442447$	
$E1 = 0.219742944$	$H1 = 0.359860715$	U1 = 0.01963299	
$E2 = 3.9108E-05$	$H2 = 5.43319E-05$	$U2 = 2.31765E-10$	
$E3s = -0.505515326$	H3s = −0.344478125	U3 = 0.02593298	
$E4s = -0.000256672$	H4s = −0.000194739	$U4 = 3.83572E-09$	

Eq (linearized point estimate) = -0.26389584		$\mathbf{U_q = (H_q - E_q)^2 = 0.054008421}$	$\boldsymbol{H_\eta = -0.031498721}$

Constant-scaled:

Eq related intermediate parameters	**Hq related intermediate parameters**	**U_q related intermediate parameters**	$\mathbf{H\eta = Eq + (Uq)^{1/2}}$
$E_D = 0.022094106$	$H_D = 0.113976896$	$U_D = 0.008442447$	
$E1 = 0.219742944$	$H1 = 0.359860715$	$U1 = 0.01963299$	
$E2 = 3.9108E-05$	$H2 = 5.43319E-05$	$U2 = 2.31765E-10$	
$E3c = -0.163644789$	$H3c = -0.111514028$	$U3 = 0.002717616$	
$E4c = -8.30895E-05$	$H4c = -6.30405E-05$	$U4 = 4.0196E-10$	
Eq (linearized point estimate) = 0.057257267		$\mathbf{U_q = (H_q - E_q)^2 = 0.030793054}$	$\boldsymbol{H_\eta = 0.232736764}$

Calculate σ_R :

$\sigma_R = \sqrt{\frac{MSB_R}{m} + \frac{(m-1)MSW_R}{m}} = \sqrt{0.163727878} = 0.4046 > 0.1$ (regulatory constant),

therefore, reference-scaled procedure applies.

Since the 95% upper confidence bound for linearized criteria of reference-scaled procedure is negative (-0.031498721), bioequivalence can be concluded.

C. Electronic Table Templates for BE Study Data

The following table templates have been developed in a concise format consistent with the Common Technical Document (CTD). For electronic submission of the individual data and summary data from the BE studies, please provide complete tables using the formats indicated below, and send them as a part of the ANDA bioequivalence submission. Submission of these electronic summary tables is necessary for improving the efficiency of the review process.

Table 1. Individual Data of In Vitro Tests Using SAS Transport Format

Batches	Container	Stage	Product	In vitro measurement (original data)
1	1	Beginning	Reference	
1	1	Middle	Reference	
1	1	End	Reference	
2	2	Beginning	Test	
2	2	Middle	Test	

2	2	End	Test	

Table 2. Summary Tables of PBE Results Using Word and/or PDF Format

Variable	Geometric Mean		Geometric Mean Ratio	Standard Deviation		SigmaT/SigmaR Ratio
	Test	Reference		SigmaT	SigmaR	

Scaled	Linearized Point Estimate	95% Upper Confidence Bound	Pass or Fail PBE
Reference-scaled			
Constant-scaled			

TABLE FORMAT FOR APSD DATA SUBMISSION:

Variable Name	Variable Type	Content	Notes
Product Name	Character	TEST or RS	Identifier for product
LOT Number	Alphanumeric/Numeric	Alphanumeric/Numeric	Identifier for product lot
UNIT Number	Numeric	Numeric values	Identifier for unit must be unique for each product (e.g., #1-30 for test and #31-60 for RS).
Stage 1	Numeric	Numeric Values	S1
Stage 2	Numeric	Numeric Values	S2
Stage 3	Numeric	Numeric Values	S3
Stage 4	Numeric	Numeric Values	S4
Stage 5	Numeric	Numeric Values	S5
Stage 6	Numeric	Numeric Values	S6
Stage 7	Numeric	Numeric Values	S7
Stage 8 or Filter	Numeric	Numeric Values	S8
ISM	Numeric	Numeric Values	ISM
MMAD	Numeric	Numeric Values	MMAD
GSD	Numeric	Numeric Values	GSD
FPM	Numeric	Numeric Values	FRM

Example:

PRODUCT	LOT	Unit	S1	S2	S3	S4	S5	S6	S7	S8 or Filter	ISM	MMAD	GSD	FPM
TEST	1234	1												
		2												
		3												
		4												
		5												
		6												
		7												
		8												
		9												
		10												

[a] For the most recent version of a guidance, check the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.